A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

BACKGROUND OF THE INVENTION

THIS invention relates to a safety assembly for a hypodermic applicator set, and in particular to a safety assembly for a hypodermic cannula set.

The needles of used syringes and cannula infusion and fluid extraction sets pose an increasing threat of transmissibility of potentially lethal infections such as HIV and hepatitis B viruses to persons handling the devices both during and after use.

In the recent past, a vast array of devices and systems for preventing contact with used needles of medical devices have been proposed. These include syringes and cannula devices extending to protecting shields or sheaths into which the devices are withdrawn after use to a position where the needle point is shrouded from accidental contact. Such shielding devices have tended to focus on syringe sets as opposed to cannula sets, in spite of the fact that the latter constitute a greater risk in view of the greater quantities of potentially contaminated blood involved and the generally jerkier movements associated with the necessity to withdraw the needle quickly from the cannula catheter and to prevent blood emission or fluid spillage while simultaneously connecting a fluid infusion or extraction tube to the catheter.

In the case of both syringe sets and cannula sets, the additional operating length of the device constituted by the protecting shield, and the additional components in the retraction mechanism employed, have contributed both to significant additional manufacturing costs and also to user inconvenience.

It is an object of the invention to provide a safety assembly for a hypodermic cannula set in which the risk of needle stick is minimized after the needle has been in contact with potentially infected blood, which is economical to produce and which is simple and convenient to use, in that the procedure does not significantly deviate from conventional catheter or cannula insertion techniques.

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided a safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a hollow needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends into mounting engagement with the needle seat, and at least one captivating formation carried on the shield, the needle assembly being slidably moveable in concert with the retractor from an extended administrable position in which the needle extends through the front end of the shield to a retracted position in which the needle is fully withdrawn into the chamber by the retractor to be held safely captive within the chamber by the captivating formation.

In the preferred from of the invention, the retractor is detachably mountable to a rear end of the needle seat and is separable from the needle seat when in the retracted position.

Conveniently, the retractor includes a pair of manually grippable outer caliper arms which are arranged to deform inwardly in response to finger pressure so as to frictionally engage an outer surface of the safety shield when the needle

assembly is in the extended administrable position, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation.

Advantageously the needle assembly and the retractor are in conjunction freely and axially slidable from the extended to the retracted positions, the caliper arms having an inner arcuate profile which corresponds to an outer arcuate profile of the safety shield.

Preferably, a needle shield is fitted over the needle when in an extended position, the needle shield being mountable to a front end of the safety shield or retractor and including detent means for detaining the needle assembly in an extended stowed position prior to use.

Typically, the needle shield and the retractor carry respective engaging and complemental engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the extended stowed position.

Advantageously, the outer caliper arms terminate in the complemental engaging formations for engaging with engaging formations on the needle shield.

Conveniently, the needle seat defines a viewing chamber for monitoring the ingress of fluid via the hollow needle, and fluid retaining filter insert means is mounted at a rear end of the viewing chamber, the filter insert means being held in position by the needle seat engaging formation at a front end of the plunger.

The filter insert means may comprise an air permeable filter disc which is mounted in a detent towards a rear end of the viewing chamber.

Conveniently, the needle seat engaging formation comprises a balled end formation which is detachably engageable with a corresponding socket recess defined at a rear and of the viewing chamber, and at least one breather gap being defined between the balled end formation and the socket recess, with the combination of the air permeable filter disc and the breather gap providing an air escape path as fluid is introduced into the viewing chamber.

Typically, the hypodermic applicator set is a hypodermic cannula set, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula or catheter tube is detachably mountable to the spigot.

Advantageously, a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter tube into the chamber, the needle extending in use through the sealing plug in the extended position and being withdrawable back through the sealing plug to the retracted position in which the sharp end of the needle is seated rearwardly of the sealing plug, the sealing plug being arranged to reseal on withdrawal of the needle.

The sealing plug may serve as a front captivating formation for preventing the needle from escaping through the front end of the safety shield when in the retracted position.

Advantageously, the captivating means comprises a retaining rib extending inwardly from a rear end of the shield, and a rearmost flange is formed at a rearmost end of the needle assembly, the flange forming a snug sliding fit with the inner wall surface of the safety shield and being provided with at least one breather gap for preventing the formation of a vacuum in that portion of the chamber between the needle assembly and the shield.

The invention extends to a method of manufacturing a safety assembly for a hypodermic applicator set comprising the steps of providing a safety shield having a front spigot end and a rear open end, fitting a catheter tube to the front spigot end of the safety shield, loading a needle assembly, which includes a needle projecting from a needle seat, through the rear open end of the shield, and driving the needle assembly into an extended position in which the needle extends through the catheter tube using a retractor having a central plunger or shaft which detachably engages a complemental formation at a rear end of the needle seat.

Preferably, the further steps of fitting a needle shield over the needle and catheter, with a rear end of the needle shield detachably engaging a front end of the retractor.

The method advantageously includes the further steps of fitting a sealing disc to the needle by piercing a sheet of disc-forming material with the needle, and using the needle as a centering axis for punching or cutting out the sealing disc.

Conveniently, the method includes the further step of locating the sealing disc towards the front end of a chamber defined within the safety shield for preventing the leakage of fluid from the catheter tube into the chamber once the needle is withdrawn into the retracted position.

The method may include the further step of punching a filter disc from a sheet of disc material, locating the filter disc within the needle seat, and retaining the filter disc in position within the needle seat by virtue of the engagement between the central plunger or shaft and the complemental formation at the rear end of the needle seat.

Typically, the assembly steps take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a perspective view of a cannula safety assembly of the invention in a stowed configuration prior to use;

Figure 2 shows a partly cross-sectional side view of the cannula safety assembly of Figure 1 just prior to use with the needle shield removed;

Figure 3 shows a partly cutaway side view of the cannula safety assembly of Figure 2 in the retracted safe position;

Figure 4 shows a detailed cross-sectional side view along the lines 4-4 of Figure 1;

Figure 5 shows a detailed cross-sectional side view of part of the needle and viewing chamber assembly in the retracted position;

Figure 5A shows an end-on rear view of the viewing chamber of Figure 5;

Figure 6 shows a perspective view of a retractor forming part of the cannula safety assembly of the invention;

Figures 7A to 7D show partly schematic diagrams of various steps in the manufacturing process whereby a sealing plug is fitted to the needle;

Figures 8A & 8B show respective partly schematic top plan and rolled out side views of various steps in an automated assembly sequence adopted during the manufacturing process.

DESCRIPTION OF EMBODIMENTS

Referring first to Figures 1 to 3, a cannula safety assembly 82 includes a round cylindrical cannula safety shield 84 having a rear open end 85, an elongate retractor 86 which fits over the safety shield 84, and a needle assembly 88 which locates within the safety shield 84 when in the retracted Figure 3 position. A cannula or catheter tube 90 is formed with a rear hollow seat portion 92 which locates in a friction fit over a spigot 94 defined at the front end of the safety shield 84. A needle cover or shield 96 is in turn fitted over the front end of the safety shield, providing a protective cover for the needle assembly 88 and cannula 90 when in the extended position.

The retractor 86 is provided with a central shaft or plunger 98 which extends through the rear open end 85 of the safety shield and terminates in a balled end 100. A pair of caliper arms 102 extend in a direction parallel to the central shaft 98, and have opposed complemental concave arcuate faces 103 which allow them to fit snugly around the safety shield, as is clear from Figure 6.

Figures 4 and 5 show clearly how the various components described above fit together when assembled. The needle assembly 88 comprises a needle 106 fitted to a transparent needle seat 108, which also defines a viewing chamber 110. A filter disc 112 is mounted in a detent channel defined by first and

second shoulders 114 and 138 respectively at a rear end of the viewing chamber, and is held firmly in position by the balled end 100 of the shaft, which in turn locates within a complemental socket-defining channel 116 located towards the rear of the needle assembly. A rubber sealing plug 118 is located snugly within the safety shield just rearwardly of the spigot 94. The sealing plug 118 is retained in position by means of a circumferential retaining rib 120 having a shallow sawtooth profile.

The needle and catheter shield 96 is dimensioned to slide snugly over the front end of the safety shield. A clip-receiving recess 122 is formed at the rearmost end of the needle shield 96, and is arranged to accommodate complemental clips 124 extending from the front end of the retractor calipers 86 when in the stowed position. The needle shield 96 and the retractor 86 thus mate with one another in a click fit to hold the entire assembly firmly together in the stowed needle-extended position.

In use, the cannula safety assembly 82 is operated as follows. Finger pressure is applied inwardly against the opposed flexible finger grips 126 at the ends of the caliper arms 102, and the needle shield is then pulled off as the clips 124 are released from the clip-receiving apertures 122. The cannula safety assembly is now in its Figure 2 condition, at which stage the practitioner continues to grip the cannula safety assembly around the finger grips 126 and introduces the sharp end 128 of the needle into the vein. The inner arcuate concave surfaces 103 of the calipers 86 deform inwardly when gripped so as to provide frictional resistance over a significant area of the outer arcuate, concave surfaces 84.1 of the safety shield. Forward pressure on the finger grips 128 is transmitted into forward pressure on the central shaft 98, which in combination with the frictional resistance between the calipers 86 and the safety shield 84 effectively overcomes any counter forces on the needle during the hypodermic insertion procedures. Once the cannula 90 is in place in the vein, which is indicated by the backflow of blood into the viewing chamber 110,

the practitioner grips the front end 130 of the safety shield to prevent the cannula catheter from dislodging from the spigot 94, and simply withdraws the retractor 86 with the other hand with lightened pressure on the finger grips 126. The needle assembly 88 can thus be freely retracted to the Figure 3 position in which the aperture formed by the needle 106 through the rubber sealing plug 118 seals off, so as to prevent the continued backflow of blood into the safety shield.

It will be appreciated that, one disengaged from the needle shield, in the absence of any click- or rotary-type detent the retractor is able to travel freely in concert with the needle assembly from the extended administering position to the fully retracted position. The entire procedure involves a smooth axially reciprocating motion which is substantially jerk free and which does not deviate significantly from a conventional a catheter insertion procedure.

A retaining rib 132 extending inwardly from the rear end of the shield serves to hold the needle assembly 88 captive within the chamber by abutting against a rearmost disc-shaped castellated flange 134 formed at the rearmost end of the needle assembly. The flange forms a sliding fit with the inner wall 136 of the safety shield, and is provided with six evenly spaced breather gaps 140 for ensuring that a vacuum is not formed in the space 141 between the needle assembly 88 and the shield 82. Further rearward force on the retractor causes the ball 100 to break away from the socket 116. During breakaway of the ball 100, additional outward pressure is exerted on the flange 134, thereby ensuring that the flange 134 is retained firmly in position behind the rib 132. The porous membrane 112, which was previously mechanically locked in position by the front face of the ball 100, is now retained by a rear shoulder 138 to prevent blood from escaping from the viewing chamber 110. The provision of both the sealing plug 118 and the filter disc 112 allow the practitioner to have sufficient time to arrange for a fluid line to be connected, without being concerned about the uncontrolled backflow of fluid through the

catheter once the needle has been withdrawn through it. The combination of the air permeable filter disc 112 and breather gaps defined by flat faces 148 on either side of the ball 100 provide an air escape path as blood is introduced into the viewing chamber 110.

Referring now to Figures 7A to 7D, the various manufacturing steps involved in locating the disc-shaped sealing plug 118 concentrically over the needle 106 are shown. The needle assembly 88 stops at a sealing plug station 149, where a sheet of sealing plug rubber 150 is located between a die and punch assembly comprising an apertured die 152A, a stripper plate 152B and a circular punch 153. The needle is positioned in such a way that it is co-axial with the axis 154 defined by the die apertures. The needle is then clamped into position by means of a pair of clamps 156, after which the punch and die assembly is moved to the right, thereby causing the needle to pierce the strip of sealing plug material 150. The sealing plug material 150 is flexible, and re-aligns itself with the needle, whereafter the punch 153 moves to the right to cut the sealing plug 118, which is now concentrically located on the needle in the correct axial position along the needle. The punch then retracts, the needle moves on, and the strip of sealing plug material 150 indexes to the next position.

The various steps involved in the manufacture and insertion of the filter disc 112 are similar to those involved in manufacturing and placing the sealing plug, in that a die and punch assembly is used to punch filter discs from an indexed sheet of filter disc material, with the punch being arranged to locate the filter disc in the appropriate position within the viewing chamber.

Figures 8A and 8B illustrate the manner in which the cannula safety assembly is manufactured in a fully automated manufacturing procedure. The entire assembly procedure takes place on a carousel 160 which rotates relative to a barrel or safety shield loading station 162, a catheter loading station 164, a

needle assembly loading station 166, a retractor loading station 168, a retractor inserting station 170 and a needle shield loading station 172. The completed assembly is rotated through one more step before being released for packaging at a packaging station 174. For ease of reference, the various stations have also been numbered from 1 to 8.

Referring now to Figure 8B, at the shield loading station 162, cannula safety shields 84 are drop loaded and then clamped in position. A string of catheters 90 is then provided in a drop tube or bandoleer , with each catheter then being individually uploaded from the drop tube or bandoleer via a reciprocating ram arrangement 176. At the needle loading station 166, a string of needle assemblies is then sequentially drop loaded into the rear open end of each needle shield 84. The needle assemblies are pre-fitted with the sealing plugs 118 and filter discs 112 in the manner described earlier on in the specification. At the retractor loading station 168, the central shafts or plungers 98 of a string of retractors 86 are drop loaded into the rear end of each needle shield 84. At the retractor inserting station 170, the retractor shaft 98 is inserted completely into the safety shield 84 by a plunger 178, thereby pushing the needle assembly through the safety shield to the Figure 2 extended position, with the ball 100 of the retractor holding the filter disc 112 in position.

At the needle shield loading station 172, the needle shields 96 are uploaded from a drop tube or bandoleer, with a ram 180 serving to urge the needle shield 96 into position in which it forms a click fit with the end of the retractor in a manner previously described. The complete cannula safety assembly 82 is then conveyed to the packaging station 174.

It is clear from the above that the cannula safety assembly of the invention lends itself readily to a high speed automated manufacturing and assembly process. This process is further speeded up by virtue of the fact that the entire assembly is mechanically fitted together, with no adhesives or bonding agents

being required in the manufacturing process apart from the bonding of the needle to the needle seat.

It will also be apparent that because the rear of the needle assembly 88 in the safe position is substantially flush with the rear of the cannula safety shield 84, the overall length of the safety shield necessary to shroud the needle point 128 in the safe position approximates closely the overall length of the needle assembly.